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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10 087,345	03.01/2002	Chung Owyang	UM-06962	3068

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10 087 345

Examiner

Daniel M Sullivan

Applicant(s)

OWYANG, CHUNG

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a) and in no event, however, may a reply be timely filed more than SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If the period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. 35 U.S.C. § 133.
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.134(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6 and 10-12, drawn to a composition, vector and host cell comprising a nucleic acid encoding an Orphanin FQ receptor (OFQR), classified in class 536, subclass 23.5.
- II. Claims 7-9, drawn to a transgenic animal comprising the host cell of group I, classified in class 800, subclass 8.
- III. Claims 13 and 14, drawn to a composition comprising an OFQR polypeptide, classified in class 530, subclass 350.
- IV. Claims 15-20, drawn to a method for screening test compounds for the ability to bind to OFQR, alter interaction between OFQR and Orphanin FQ or bind to OFQR, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Invention I are related to the protein of Invention III by virtue of encoding the same. Further, the DNA molecule has utility for the recombinant production of the protein in host cells. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the

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natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The protein of Invention III and nucleic acid of Invention I are related to the transgenic animal of Invention II in that the animal can be produced using the nucleic acid of Invention I and might comprise the protein of Invention III. The animal is distinct from the protein and nucleic acid, however, because they are physically and functionally distinct and the peptide and nucleic acid can be used for processes other than production of the transgenic animal, such as to raise antibodies, or screen for agents that bind to the protein or nucleic acid. Furthermore, patentability of the transgenic animal arises from the phenotypic characteristics of the animal; thus, patentability of the transgenic animal is not solely dependent upon the particulars of the nucleic acid or polypeptide comprised within the animal.

Inventions I-III are each related to Invention IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process as claimed could be practiced using any of the products of Inventions I-III. Furthermore, each of the products can be used in materially different processes. For example the nucleic acid of Invention I can be used in hybridization assays such as to screen a library, the transgenic animal of Invention II can be used to study the physiological consequences of overexpression or knockout of the OFQR gene and the polypeptide of Invention III can be used to raise an antibody.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, or because each of the distinct inventions comprise distinct elements and therefore cannot be searched coextensively, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
July 23, 2003

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER